Impact of State Certificate of Need Programs on Outcomes of Care for Patients Undergoing Coronary Artery Bypass Surgery

Report to the Florida Hospital Association

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Project Objectives

This principal aim of the current analysis was to examine the potential impact of state Certificate of Need (CON) programs on the delivery of care to patients undergoing coronary artery bypass graft (CABG) surgery. The analysis addressed this aim by comparing outcomes of CABG in states with and without CON programs. The analysis utilized claims data for Medicare beneficiaries from all 50 states for a 6-year period (fiscal years 1994 through 1999). All data were obtained from the Health Care Financing Administration (HCFA).

The specific objectives of the analysis were to compare the following outcomes in states with and without CON programs:

1. Severity of illness of patients undergoing CABG and proportions of patients with specific "risk factors."
2. Risk-adjusted in-hospital mortality rates.
3. Percent of patients undergoing CABG in "low-volume" hospitals.
4. Utilization rates for CABG.

These outcomes were chosen for specific reasons. The severity of illness of patients undergoing CABG, proportion of patients with specific risk factors, and utilization rates examine the degree to which the presence of CON programs was associated with different practice patterns for performing CABG. For example, CON programs may decrease the use of CABG in situations in which indications for CABG are equivocal (e.g., patients at lower risk of cardiac complications or with lower severity of illness). Risk-adjusted mortality rates are likely to reflect quality of care and have been widely used as measures of institutional performance. It is possible that CON programs result in higher quality of care for patients undergoing CABG. If true, risk-adjusted mortality rates may be lower in states with CON programs. Lastly, the proportion of patients undergoing CABG in low-volume hospitals is also likely to be an indicator of hospital quality, given the well-established relationships between hospital volume and patient outcomes for numerous surgical procedures and for non-surgical conditions. The absence of CON programs may lead to the establishment of more low-volume cardiac surgery programs.

METHODS

Data: All analyses utilized Medicare Provider and Analysis Review (MEDPAR) Part A data files. The Part A files contain data available on the UB-92 hospital discharge abstract for Medicare patients discharged from acute care hospitals and other types of facilities and have been extensively used in health services research (1). Data elements include: demographic information; patients' state of residence; primary and secondary diagnoses and procedures, as captured by ICD-9-CM codes; DRG; discharge disposition; total and departmental charges; and a six digit unique facility identifier. The Part A files contain records for 100% of Medicare beneficiaries who use hospital inpatient services during a given year (roughly 11 million records per year). Patients undergoing CABG in calendar years 1994-1999 were identified in the Part A files using DRGs 106, 107, and 109 (DRG 109 became effective in October 1998). Additional information on the number of Medicare beneficiaries aged 65 years and older with either Medicare hospital insurance or supplemental insurance in each state was obtained from the HCFA website. Because this level of information was only available for the years 1998 and 1999, analyses utilized the mean number of beneficiaries for the two years.

Individual states (and the District of Columbia) were categorized according to whether they had a CON program in effect during the observation period. Three CON categories were defined: 1) states that had a CON program continuously from 1994 through 1999 (i.e., "continuous CON"), 2) states that terminated CON programs prior to 1994 (CA, SD, CO, AZ, KS, WY, TX, NM, UT, ID; i.e., "no CON"); and 3) states that terminated and/or reinstated CON programs from 1994 through 1999 (MN, ND, PA, IN; i.e., "intermittent CON"). Of the states categorized as having intermittent CON, two states (MN and ND) repealed CON regulations in 1996, one state (PA) repealed CON in 1997, and one state (IN) repealed CON in 1996, reinstated CON in 1997, and then repealed CON in 1999. Hospitals in each state were identified using the Medicare provider number.

Analytical Steps: The analysis involved four steps.

First, unadjusted in-hospital mortality rates in the three categories of states were compared using the chi-square test. The mean annual CABG volume per hospital in states with continuous, intermittent, and no CON regulation was compared using analysis of variance. In addition, hospitals were categorized according to mean annual CABG volume, and the percent of patients treated at low volume hospitals were compared across the types of CON. These analyses utilized several alternative cut-off points for low volume—less than 50 Medicare cases annually, less than 100 cases, and less than 250 cases.

CABG utilization rates were compared for residents in states with continuous, intermittent, and no CON regulation determined by dividing the total number of CABG procedures performed (based on patients' state of residence) by the total number of Medicare beneficiaries. Utilization rates were then expressed as the number of procedures performed per 1000 beneficiaries.

Second, patient risk factors that could be used in developing a risk adjustment model were identified in the MEDPAR data. Risk factor variables included race, gender, age, admission source, and several conditions, represented by ICD-9-CM diagnosis and procedure codes that were previously identified by Hannan et al. (*Medical Care 1992; 30(10):892-907; Health Services Research 1997; 31(6):659-678*) as risk factors for mortality in patients undergoing CABG . ICD-9-CM risk factor definitions are shown in Table 1 below.

Table 1. ICD-9-CM Risk Factor Definitions

Risk Factor	ICD-9-CM Code
Acute Myocardial Infarction	410.X
Congestive Heart Failure	402.01, 402.11, 402.91, 402.92, 425.0, 428.X
Cerebrovascular Disease	362.34, 430-438, 781.4, 784.3, 997.0
Peripheral Vascular Disease	440.2, 441.X, 443.9, 444, 447.1, 785.4
Diabetes mellitus	250.X, excluding 250.00
Chronic obstructive pulmonary disease	491, 492, 496
Cardiac catheterization on date of CABG	37.21 –37.23
Percutaneous transluminal coronary angioplasty on data of CABG	36.01-36.01, 36.05
Use of intra-aortic balloon pump (IABP)	37.61-37.62

Third, using these risk factors, a risk-adjustment model was developed. Candidate variables associated ($P<.1$) with in-hospital mortality (as determined by the discharge disposition variable) in bivariate analyses were entered into a stepwise logistic regression to identify variables independently related to mortality using a statistical criterion of $P<.05$. Variables in which the direction of the statistical association was contrary to previously described relationships were excluded from the model. In addition, several risk factors that could represent complications of CABG and not necessarily pre-existing conditions, such as cardiogenic shock and renal failure, were not included in the model. Discrimination of the model was evaluated using the c-statistic, and calibration was assessed using the Hosmer-Lemeshow statistic.

The risk adjustment model was then used to determine a predicted risk of death (0 to 100%) for all patients in the analysis. The mean predicted risk of death served as a summative measure of the severity of illness of individual patients.

The prevalence of individual risk factors in continuous, intermittent, and no CON regulation was compared using the chi-square test. The mean predicted risk of death across the three CON categories was compared using analysis of variance. Nearly all statistical comparisons of individual risk factors and comparisons of predicted risk of death were statistically significant, given the very large sample sizes. However, most differences were very small in magnitude.

Thus, statistical significance was not reported for these comparisons, so that undue importance would not be placed on very small differences. Instead, readers can make their own assessments of the clinical and practical importance of the differences reported.

Fourth, differences in risk-adjusted mortality across states were examined using two different methodological approaches.

The first approach compared differences in mortality in states with continuous, intermittent, and no CON regulation by including additional indicator variables in the logistic regression model for states with intermittent and states with no CON regulation. The regression coefficients associated with the two indicator variables were then used to determine the adjusted odds of death of patients in these two groups, relative to patients in states with continuous CON. Odds higher than 1.0 would indicate that the risk-adjusted mortality was higher than in states with continuous CON, while odds of death lower than 1.0 would indicate that risk-adjusted mortality was lower than in states with continuous CON. This analysis was repeated including individual indicator variables for each state with no or intermittent CON regulation. This approach provided adjusted odds of death for individual states with either no or intermittent CON, relative to all states with continuous CON.

The second approach examined comparisons of mortality in all 50 states by determining the ratio of observed to predicted (O / P) deaths for each state. The number of predicted deaths was determined by aggregating the predicted risks of death of individual patients hospitalized in each state to determine the total number of deaths predicted on the basis of the risk-adjustment model. Observed to predicted (O / P) ratios higher than 1.0 indicate that actual mortality was higher than expected (i.e., worse performance). O / P ratios lower than 1.0 indicate that actual mortality was lower than expected (i.e., better performance). The statistical significance of all O / P ratios was determined by dividing the difference in observed and predicted mortality rates by the standard error of the difference. The P value associated with the resulting statistic was then reported.

All analyses were limited to patients 65 years and older. In addition, a small number of hospitals in the HCFA MEDPAR data reported extremely low CABG volumes over the 6 year period. Patients discharged from hospitals in a year in which the hospital had 5 or fewer CABG procedures in the MEDPAR data (n=333 total cases) were assumed to be coding errors and likely not valid CABG procedures. Those records were eliminated from the analysis. These exclusions eliminated 0.04% of patients, and thus, did not impact the results of the analysis.

RESULTS

Patient Characteristics: Characteristics of patients according to state CON regulation status are shown in Table 2, below. Age distributions of patients were relatively similar in the three groups, although patients in states with no CON were somewhat less likely to be female, to be white, and to be classified as an admitted emergency admission. Patients in states with no CON were somewhat more likely to be admitted or referred from a physician's office, clinic, or HMO.

Table 2) Patient Characteristics According to State CON Regulation Status

	Continuous CON	No CON	Intermittent CON
Total Number of Patients	***643,953***	***167,933***	***99,521***
Female Gender	35.0%	32.8%	36.4%
Age (years)			
65 to 69	29.2%	28.9%	28.0%
70 to 74	32.5%	32.1%	33.0%
75 to 79	25.0%	25.1%	25.9%
80 to 84	10.7%	11.1%	10.7%
85 to 89	2.3%	2.6%	2.2%
90 and Older	0.2%	0.2%	0.2%
Mean ± SD	73.2 ± 5.3	73.3 ± 5.4	73.3 ± 5.3
Race			
White	92.7%	89.0%	95.2%
Black	4.2%	2.6%	2.4%
Other	2.4%	7.7%	1.7%
Missing Race	0.7%	0.7%	0.7%
Admission Type			
Emergency	28.7%	22.1%	33.8%
Urgent	31.9%	36.6%	26.7%
Elective	38.9%	41.0%	39.4%
Admission Source			
Physician / Clinic / HMO Referral	57.2%	63.4%	58.0%
Transfer from other acute care hospital	21.1%	14.6%	21.1%
Transfer from other type of inpatient facility	2.4%	1.4%	2.5%
Emergency Room	18.9%	19.9%	18.2%
Other/Unknown	0.4%	0.6%	0.1%

Unadjusted in-hospital mortality rates of patients in states with no CON were higher ($p<.001$) than mortality rates in patients in states with either continuous CON or intermittent CON (4.3% vs. 3.7% and 3.5%, respectively; Table 3, below). In addition, patients in states with no CON were somewhat less likely to be discharged with home health services. In all the groups, volumes during the 6-year period (as summarized by the percent of discharges by year increased from 1994 to 1996 and then decreased from 1997 to 1999. Comparing changes in volume between 1994 and 1999, CABG volumes increased 2.4% in states with continuous CON and decreased 4.1% and 7.4%, respectively, in states with no and intermittent CON.

Table 3) Discharge Disposition and Year of Discharge According to State CON Regulation Status

	Continuous CON	No CON	Intermittent CON
Discharge Disposition			
Home/Self Care	60.8%	63.0%	59.4%
Transferred to other ST hospital	0.6%	0.8%	0.6%
Transferred to other facility	12.1%	14.6%	15.4%
Home Health Service	22.8%	17.1%	21.0%
Died	3.7%	4.3%	3.5%
Other	0.1%	0.2%	0.1%
Year of Discharge			
1994	15.5%	15.8%	16.2%
1995	16.8%	16.8%	17.4%
1996	17.8%	18.1%	18.1%
1997	17.6%	17.8%	17.5%
1998	16.4%	16.4%	15.9%
1999	15.8%	15.1%	15.0%
Percent Change in Volume (1994 to 1999)	2.4%	- 4.1%	- 7.4%

Prevalence of Risk Factors and Severity of Illness: The prevalence of individual comorbid conditions and "high-risk" clinical conditions was generally similar in the three groups (Table 4), and mean numbers of comorbid and high-risk conditions were identical. In addition, the mean predicted risk of death was nearly identical, as were proportions of patients with greater than 10% predicted risk of death. The predicted risk of death represents a summary of all individual risk factors (i.e., severity of illness). The similarity of this measure across groups suggests that patients undergoing CABG in the three groups were clinically similar.

A somewhat lower percentage of patients in states with continuous CON underwent cardiac catheterization or PTCA during the admission for CABG, while a somewhat higher percentage of patients in states with no CON had the CABG performed on the same day as a cardiac catheterization or a PTCA (12.6% vs. 9.0% and 8.2%, respectively, in states with continuous and intermittent CON. A somewhat lower percentage of patients in states with no CON had a primary diagnosis of acute myocardial infarction.

Table 4) Risk Factors and Severity of Illness According to CON Regulation Status

	Continuous CON	No CON	Intermittent CON
Comorbid Conditions			
Diabetes Mellitus	10.2%	9.8%	10.1%
Chronic Obstructive Pulmonary Disease	14.2%	14.5%	14.1%
Congestive Heart Failure	18.8%	18.8%	20.1%
Cerebral Vascular Disease	10.2%	9.1%	9.7%
Peripheral Vascular Disease	8.5%	7.7%	9.0%
Number of Comorbid Conditions			
0	54.4%	55.8%	54.0%
1	31.7%	31.1%	31.8%
2	11.4%	11.0%	11.8%
3 or More	2.4%	2.3%	2.5%
Mean ± SD	0.6 ± 0.8	0.6 ± 0.8	0.6 ± 0.8
DRG with PTCA or Cardiac Catheterization	59.4%	65.7%	63.8%
High Risk Clinical Conditions			
Primary Diagnosis of Acute MI	20.1%	19.0%	20.7%
Cardiogenic Shock	1.4%	1.7%	1.8%
Cardiac Cath. on same day as surgery	7.8%	10.8%	7.0%
PTCA on same day as CABG	1.2%	1.8%	1.2%
IABP prior to day of CABG	3.0%	2.8%	3.9%
Number of High Risk Clinical Conditions			
0	73.2%	72.0%	72.8%
1	23.0%	23.5%	23.0%
2 or More	3.9%	4.5%	4.3%
Mean ± SD	0.3 ± 0.5	0.3 ± 0.5	0.3 ± 0.5
Predicted Risk of Death			
< 2%	36.0%	36.2%	34.9%
2 – 5%	43.8%	43.5%	43.5%
5 – 10%	15.1%	14.9.5%	15.9%
Greater than 10%	5.1%	5.3%	5.7%
Mean ± SD	3.8% ± 3.6%	3.8% ± 3.7%	3.9% ± 3.8%

Risk Adjusted Mortality: Fourteen variables were included in the final logistic regression risk-adjustment model: age (categories 65-69, 70-74, 75-79, 80-84, 85-89, 90 plus), gender, race (categories white, black, other non-white), primary diagnosis of acute myocardial infarction, congestive heart failure, cerebral vascular disease, diabetes, peripheral vascular disease, chronic obstructive pulmonary disease, PTCA on the same day as CABG, cardiac catheterization on the same day as surgery, and use of an intra-aortic balloon pump (IABP) prior to CABG. Odds ratios associated with each of the variables are shown in Appendix A. The c-statistic of the model was 0.725, indicating "good" discrimination.

In analyses using data for all 6 years, the odds of death in states with no CON was 1.18 (95% CI, 1.15 – 1.22, p<.001). This suggests that the overall risk of in-hospital death was 18% higher for patients in states with no CON, relative to patients in states with continuous CON. The odds ratio for states with intermittent CON was 0.91 (95% CI, 0.88 0.95, p<.001), indicating that patients in states with intermittent CON had, on average, a 9% lower risk of death, relative to patients in states with continuous CON.

The above relationships were generally consistent across individual years, as shown in Table 5, below. For each of the 6 years, the risk-adjusted odds of death of patients in states with no CON were significantly higher than in patients in states with continuous CON, although the differences in the risk-adjusted odds of death tended to decline over time (i.e., from 26% higher in 1994 to 13% higher in 1999). Risk-adjusted odds of death were similar or somewhat lower in states with intermittent CON, compared to states with continuous CON when individual years were examined.

Table 5) Risk-adjusted odds of death in patients in states with no CON and with intermittent CON, relative to patients in states with continuous CON, for individual years

Year	No CON			Intermittent CON		
	Odds Ratio	*P Value*	*95% CI*	*Odds Ratio*	*P Value*	*95% CI*
1994	1.26	<.001	1.18 – 1.34	0.97	0.50	0.89 - 1.06
1995	1.21	<.001	1.13 – 1.29	0.93	0.10	0.86 - 1.02
1996	1.15	<.001	1.08 – 1.23	0.92	0.06	0.84 - 1.00
1997	1.17	<.001	1.09 – 1.25	0.85	<.001	0.78 - 0.93
1998	1.16	<.001	1.08 – 1.25	0.88	0.01	0.80 - 0.97
1999	1.13	.001	1.05 – 1.22	0.91	0.05	0.82 - 1.00

Further analyses were conducted examining the odds of death in individual states with no CON or with intermittent CON (Table 6, below).

Of the 10 states with no CON, the odds of death were higher than 1.0 for 8 states. Of these 8 states, odds ratios were statistically significant (i.e., $p<.05$) in 4 states.

Two states with no CON had odds of death that were lower than 1.0, although only one of these odds ratios was statistically significant.

Of the 4 states with intermittent CON, the odds of death were lower than 1.0 for two states. In one of these states, the odds ratio was statistically significant.

Table 6) **Risk-adjusted odds of death of patients in individual states with no CON and with intermittent CON, relative to patients in states with continuous CON for the period 1994-99**

No CON			Intermittent CON		
State	*Odds Ratio*	*P Value*	*State*	*Odds Ratio*	*P Value*
CA	0.99	.64	**PA**	0.85	<.001
CO	1.08	.22	**IN**	1.04	.33
AZ	1.42	<.001	**ND**	1.04	.60
KS	1.10	.09	**MN**	0.97	.51
WY	1.16	.45			
TX	1.40	<.001			
UT	1.22	.006			
NM	1.12	.26			
ID	1.39	.001			
SD	0.63	<.001			

Finally, risk-adjusted mortality in individual states was examined by determining ratios of observed to predicted (O / P) deaths. These data are shown in Table 7 on the following page for all 6 years in aggregate and in Appendix B for each year. As can be seen in Table 7, among the 10 states without CON, 4 had O/P ratios significantly ($p<.05$) higher than 1.0, and 1 had an O/P ratio significantly lower than 1.0.

Table 7) **Ratios of Observed to Predicted (O / P) Deaths for Individual states During the Period 1994 through 1999 According to CON Status**

State	O / P Ratio	P Value	State	O / P Ratio	P Value
Continuous CON			***Continuous CON***		
AK	0.98	.93	RI	1.06	.47
AL	1.12	<.001	SC	1.21	<.001
AR	1.10	.02	TN	1.00	.99
CT	0.94	.12	VA	0.82	<.001
DE	0.91	.37	VT	1.09	.48
FL	0.96	.04	WA	1.04	.32
GA	1.19	<.001	WI	1.10	.003
HI	1.51	<.001	WV	0.95	.30
IA	1.11	.02	DC	1.07	.28
IL	0.94	.009			
KY	1.09	.01	***No CON***		
LA	1.19	<.001	AZ	1.34	<.001
MA	0.72	<.001	CA	0.97	.07
MD	0.96	.43	CO	1.05	.40
ME	1.05	.53	ID	1.33	.003
MI	0.92	.003	KS	1.07	.21
MO	0.98	.57	NM	1.08	.42
MS	1.22	<.001	SD	0.63	<.001
MT	1.11	.23	TX	1.33	<.001
NC	0.87	<.001	UT	1.18	.02
NE	1.14	.01	WY	1.12	.52
NH	0.79	.009			
NJ	1.04	.25	**Intermittent CON**		
NV	1.46	<.001	IN	1.01	.70
NY	0.67	<.001	MN	0.95	.26
OH	0.96	.11	ND	1.02	.82
OK	1.20	<.001	PA	0.84	<.001
OR	0.99	.90			

Among the 36 states and the DC with continuous CON listed in Table 7, 13 had O/P ratios significantly higher than 1.0, and 6 had an O/P ratio significantly lower than 1.0. The greater number of continuous CON states with O/P ratios greater than 1.0 reflects the fact that the states with high O/P ratios tended to be states with smaller population, while the states with low O/P ratios tended to be states with larger populations (e.g., NY, IL, MI).

One state with intermittent CON had an O/P ratio significantly lower than 1.0.

Hospital Volume: Mean annual CABG volumes (for Medicare beneficiaries aged 65 years and older) of hospitals in states with continuous CON were higher than in states with no CON (Table 8). The mean annual hospital volume across all 6 years of 176 in states with continuous CON was 86% higher than the mean annual hospital volume of 94 in states with no CON. In contrast, mean annual hospital volumes in states with intermittent CON were relatively similar to states with continuous CON (e.g., 161 vs. 176 for all 6 years). These data are shown by individual state in Appendix C.

Table 8) Mean Annual Hospital Volumes of Medicare Beneficiaries Age 65 Years and Older

Year	Continuous CON		No CON		Intermittent CON	
	Number of Hospitals	*Mean Annual Volume (SD)*	*Number of Hospitals*	*Mean Annual Volume (SD)*	*Number of Hospitals*	*Mean Annual Volume (SD)*
1994-1999	**635**	**176 (149)**	**317**	**94 (84)**	**111**	**161 (125)**
1994	561	178	276	96	92	175
1995	563	193	280	100	94	184
1996	565	203	284	107	93	194
1997	574	197	290	103	97	180
1998	578	183	287	96	102	155
1999	590	173	291	87	102	146

Table 9, below, shows the number of hospitals performing CABG in specific volume categories and the percentage of patients undergoing CABG in hospitals within these categories. In states with continuous CON, of the 635 hospitals performing CABG, 16% of hospitals had mean annual volumes of 50 or less, and 22% had mean annual volumes of 51 to 100. In states with intermittent CON, of the 111 hospitals performing CABG, the respective percentages were 12% and 30%. However, in states with no CON, of the 317 hospitals performing CABG, 34% of hospitals had mean annual volumes of 50 or less, and 33% had mean annual volumes of 51 to 100. As also shown in Table 9, higher percentages of patients in states with no CON underwent procedures in hospitals with lower volumes.

Table 9) **Number of Hospitals in Specific Volume Categories and the Percent of Patients Undergoing CABG in Hospitals in the Volume Categories During 1994 to 1999** (Volumes based on Medicare beneficiaries 65 years and older)

Mean Annual Hospital Volume	**Continuous CON**		**No CON**		**Intermittent CON**	
	Number of Hospitals	**Percent of Patients**	***Number of Hospitals***	**Percent of Patients**	***Number of Hospitals***	**Percent of Patients**
≤ 50	100	2.5%	107	10.3%	13	2.5%
51 – 100	139	9.6%	104	25.0%	33	13.8%
101 – 250	253	37.4%	88	43.3%	45	41.2%
251 – 500	118	35.6%	17	19.3%	17	33.0%
501 – 1000	24	14.0%	1	2.1%	3	9.5%
> 1000	1	0.9%	0	0.0%	0	0.0%

The differences in percentages of patients undergoing CABG in low-volume hospitals is more clearly shown in Table 10. Using three pre-determined thresholds for "low-volume" (less than 50 cases annually, less than 100 cases annually, and less than 250 cases annually), the percentages of patients undergoing CABG in low-volume hospitals in states with no CON were substantially greater than in states with continuous CON. This relationship was consistent across the six years, when each year was examined individually. The percentages of patients undergoing CABG in low volume hospitals in states with intermittent CON were either similar or somewhat higher than in states with continuous CON, but were lower than in states with no CON.

Table 10) **Percent of Patients Undergoing CABG in Low Volume Hospitals for Different Annual Low Volume Thresholds** (Volumes based on Medicare beneficiaries 65 years and older)

Low Volume Threshold	*Year*	**Continuous CON** **Percent of Patients**	**No CON** **Percent of Patients**	**Intermittent CON** **Percent of Patients**
≤ 50	**1994 – 1999**	**2.5%**	**10.3%**	**2.5%**
	1994	2.3%	11.5%	2.0%
	1995	2.0%	9.8%	2.0%
	1996	1.8%	7.7%	1.8%
	1997	1.7%	8.2%	2.2%
	1998	2.3%	9.9%	2.3%
	1999	2.8%	13.4%	2.4%
≤ 100	**1994 – 1999**	**12.1%**	**35.3%**	**16.3%**
	1994	10.1%	36.1%	13.7%
	1995	8.5%	33.2%	9.7%
	1996	8.3%	30.0%	9.0%
	1997	8.6%	30.2%	12.3%
	1998	9.8%	38.1%	15.2%
	1999	12.0%	40.2%	20.6%
≤ 250	**1994 – 1999**	**49.5%**	**78.6%**	**57.5%**
	1994	51.8%	76.3%	55.3%
	1995	46.0%	77.1%	46.2%
	1996	42.2%	77.5%	49.2%
	1997	43.6%	74.1%	52.4%
	1998	49.5%	77.8%	60.3%
	1999	51.8%	79.4%	66.3%

CABG Utilization: Table 11 shows average annual CABG utilization rates per 1000 Medicare beneficiaries aged 65 and older. Data is organized based on state of patients' residence and not the state in which the procedure was performed. Utilization rates were lower in states with no CON, while rates in states with continuous and intermittent CON were very similar. For example, the overall rate annual rate in states with no CON was 3.89 per 1000 beneficiaries, compared to 4.79 per 1000 beneficiaries in states with continuous or intermittent CON—a 19% lower rate in states with no CON.

These results were similar if the average of individual state utilization rates was determined states in the three groups. However, the difference in CABG rates between states with continuous CON and no CON was smaller (4.71 vs. 4.41 per 1000). This largely reflected the lower utilization rate in California and the "unweighting" of the state's large CABG volume in the latter calculation.

Results were also similar in analyses that only included patients who had the CABG performed in their state of residence—i.e., excluding out-of-state procedures.

Table 11) CABG Utilization Rates (*per 1000 Medicare Beneficiaries*) During 1994 through 1999

	Continuous CON	No CON	Intermittent CON
Average Annual Number of CABG Procedures by State of Residence	108,353	27,668	15,657
Number of Medicare Beneficiaries	22,599,767	7,123,872	3,271,962
Overall Annual Rate of CABG	**4.79**	**3.89**	**4.78**
Average Annual State CABG Rate (mean of individual state rates)	4.71	4.41	4.88
Annual Rate of In-State CABG Procedures (excludes out-of-state procedures)	**4.23**	**3.62**	**4.33**
Average Annual In-State CABG Rate (mean of individual state rates; excludes out-of-state procedures)	4.04	3.58	4.31

Finally, examination of utilization rates in individual states revealed substantial variability within individual CON groups. These data are shown in Appendix D. For example, among states with continuous CON, CABG utilization rates ranged from 2.50 (DC) to 6.95 (WV). Among states with no CON, CABG utilization rates ranged from 3.20 (CA) to 5.89 (SD). Among states with intermittent CON, CABG utilization rates ranged from 4.12 (MN) to 5.40 (ND).

SUMMARY

The current analysis represents one of the first large-scale evaluations of the potential impact of CON regulation on patient outcomes and on service use. The analysis had several important strengths. First, it included patients from all 50 states. Second, it examined patients undergoing CABG over a 6-year period from 1994 to 1999—a period during which US health care delivery experienced substantial change. Third, the study utilized risk-adjustment models based on variables that had been used in prior studies and for which clearly defined algorithms existed. The risk-adjustment that was developed had good discrimination, as measured by the C statistic.

Key Findings

- Risk-adjusted in-hospital mortality (as measured by the adjusted odds of death) was 18% higher in patients in 10 states that had no CON regulation during the period 1994 through 1999, compared to patients in 36 states in which there was continuous regulation during this period. Moreover, the higher mortality in states with no CON was observed in all 6 years of the study period, although the differences in mortality tended to decline over time—from 26% in 1994 to 13% in 1999. The significance of this latter observation is unclear.

- Interestingly, risk-adjusted mortality was 9% lower in patients in the 4 states in which CON status changed during the study period. Given that much of this difference was driven by a 15% lower risk of death in one state, Pennsylvania, the significance of this finding is uncertain. Moreover, statistically significant differences in mortality were only observed in 3 of the 6 years. In addition, each of the four states with intermittent CON regulation repealed CON requirements in 1996 or 1997, and one state reinstated CON for a 2-year period. It is reasonable to assume that changes in practice patterns, as a result of the change in CON status would not be observed immediately. Thus, it is likely that the practice behavior in these four states would resemble practice behavior in states with CON to a greater degree than practice behavior in states with no CON.

- Mean patient volume in states with continuous CON was 86% higher than in states with no CON (176 case per year vs. 94 cases per year). In addition, a substantially higher proportion of patients in states with no CON regulation underwent CABG in low-volume hospitals. This finding was consistent using three different thresholds for low volume. For example, using a threshold of 50 cases per year in Medicare beneficiaries, four times as many patients underwent CABG in low volume hospitals in states with no CON, compared to states with continuous CON (10.3% of patients vs. 2.5% of patients). While there may be additional unmeasured factors (other than CON regulation) that may explain these differences (e.g., differences in population density or managed care penetration), a strong a priori hypothesis of this analysis was that the absence of CON requirements would lead to the development of low-volume CABG programs. Moreover, given the well-known relationships between hospital volume and patient outcomes for CABG and other surgical procedures, this finding may explain the higher risk-adjusted mortality in states with no CON regulations. Interestingly, the proportions of patients undergoing CABG in low volume hospitals in states with intermittent CON was relatively similar to proportions in states with continuous CON. Again, this observation may explain the relatively similar mortality in states with continuous and intermittent CON. It also provides further evidence of the general similarity of practice behavior between states with continuous CON and states with intermittent CON.

- CABG utilization was lower in states with no CON, compared to states with either continuous CON or with intermittent CON. While this finding was somewhat unexpected, most of the lower utilization was explained by the very low rates of CABG in California, a state with a high presence of managed care and with low utilization of hospital services and other surgical procedures. Indeed, if California was excluded from analysis, the resulting average annual utilization rate per 1000 Medicare beneficiaries in states with no CON (4.50) was relatively similar to the rates in states with continuous and intermittent CON (4.79 and 4.78 respectively). In addition, an important caveat is that it is difficult to interpret utilization rates without considering potential differences in patient populations or potential differences in physician density.

- The distribution of individual comorbid conditions and "high-risk" clinical conditions was very similar across the three groups, and the mean predicted risk of death (as determined by the multiple logistic regression risk-adjustment model) was nearly identical. These findings suggest that CON status was not associated with the severity of illness of patients undergoing CABG, and that there were no systematic differences in the selection of individual patients for CABG.

Potential Methodological Limitations

In interpreting the findings in this report, it is important to be cognizant of potential methodological limitations. Several of these limitations are inherent in analyses that are based on observational (i.e., nonrandomized) study designs and/or on administrative data.

- First, the analysis was limited to Medicare beneficiaries and, thus, only includes roughly half of all patients undergoing CABG. However, it is likely that if patterns of care were different for Medicare patients, relative to other patients, these differences would be similar across states and would not bias study findings.

- Second, the relationships in this observational analysis represent associations—not necessarily cause and effect relationships. Thus, any associations between CON regulation and study outcomes may represent confounding due to other factors that may differ according to CON status. These factors may include: i) managed care penetration; ii) regional physician practice variation and/or differences in quality of care; iii) efforts to report and disseminate outcomes data to providers, purchasers, and the lay public; and iv) differences in patient preferences for care. Nonetheless, it would be nearly impossible and certainly not feasible to design a study in which states were randomized to implement CON or an observational study in which all possible confounding factors could be adjusted to isolate the true effect of CON regulation.

- Third, the analysis may also be confounded by regional differences in the use of PTCA. As an alternative treatment for coronary insufficiency, such differences in PTCA use may directly impact CABG utilization and lead to selection bias in analyses comparing in-hospital mortality. Indeed, the decline in the total numbers of CABG performed in all three groups between 1996 and 1999 probably reflects increasing utilization of PTCA. Thus, full understanding of CABG utilization patterns requires analysis of PTCA utilization rates, which are beyond the scope of the current analysis.

- Fourth, the development of risk-adjustment models based on administrative data is itself subject to limitations. Administrative data may be subject to wide variations across hospitals in the reliability of individual diagnosis codes, which are used to define risk-adjustment variables. It is also difficult to discern whether certain conditions that are identified were present prior to a patient's admission or if the diagnosis occurred after CABG and may represent a complication of the procedure. However, it should be noted that the risk-adjustment was constructed to minimize the use of variables that could represent complications. The range of variables that can be used for risk-adjustment is also limited. For example, important prognostic variables, such as left ventricular ejection fraction, admission vital signs, and other admission physiological indicators cannot be ascertained from administrative data.

- Fifth, analyses of risk-adjusted mortality were based on in-hospital outcomes and did not account for outcomes that may have occurred after hospital discharge and that may be attributable to the incident hospitalization in which the CABG was performed. Although it would have been preferable to use an endpoint that is not subject to differences in hospital discharge practices, such as 30-day (post-admission) mortality, obtaining post-discharge follow-up data is costly and was beyond the scope of the current analysis.

- Lastly, the analysis used risk-adjusted in-hospital mortality as an indicator of quality of care, but did not directly measure the process of care (e.g., technical skills of the surgeon, quality of post-operative care). Similarly, the study examined CABG utilization, but did not directly examine appropriateness of CABG in individual patients.

Conclusions

The current analysis, based on a complete sample of Medicare beneficiaries undergoing CABG during the years 1994 through 1999, found that CABG utilization may actually be lower in states with no CON regulations than in states with continuous CON regulation. However, the analysis found no systematic differences in the prevalence of individual risk factors or in the predicted risk of death (i.e., severity of illness).

In contrast, the analysis found that risk-adjusted in-hospital mortality was 18% higher in states with no CON regulation, compared to states with continuous CON regulation. Based on an actual mortality rate of 37 in-hospital deaths per 1000 patients in states with continuous CON, the 18% difference in mortality would translate to 7 additional deaths for every 1000 patients undergoing CABG. In addition, the analysis found that average hospital volumes in states with no CON were substantially lower and that patients in such states were substantially more likely to undergo CABG in low-volume hospitals. The higher proportion of patients undergoing CABG in low-volume hospitals may underlie the higher risk-adjusted mortality in states with no CON. While the potential methodological limitations listed above need to be considered in the interpretation of these findings, this analysis would suggest that CON regulation is associated with better patient outcomes. Thus, repeal of CON regulations may have negative consequences on patient outcomes.

APPENDICES

Appendix A) **Risk factors included in the logistic regression risk-adjustment model. For each risk factor, the table shows the odds of death associated with the risk factor, the multivariate P value, and the 95% CI.**

Risk Factor	Odds Ratio	P Value	95% CI	
			Lower	*Upper*
DRG with PTCA or Cardiac Catheterization	1.04	.002	1.02	1.07
Female Gender	1.29	<.001	1.26	1.32
Age 70 to 74 years *	1.21	<.001	1.17	1.25
Age 75 to 79 years	1.53	<.001	1.48	1.56
Age 80 to 84 years	2.03	<.001	1.96	2.10
Age 85 to 89 years	2.48	<.001	2.34	2.63
Age 90 years and older	3.40	<.001	2.93	3.95
Race = Black †	1.20	<.001	1.14	1.27
Race = Other non-white	1.12	<.001	1.06	1.19
Primary diagnosis of acute MI	1.42	<.001	1.39	1.46
Diabetes Mellitus	1.06	.003	1.02	1.09
COPD	1.19	<.001	1.16	1.23
Congestive Heart failure	2.25	<.001	2.20	2.31
Cerebral Vascular Disease	2.33	<.001	2.27	2.40
Peripheral Vascular Disease	1.44	<.001	1.39	1.49
Emergent procedure	1.19	<.001	1.16	1.22
Cardiac catheterization on same day as CABG	1.72	<.001	1.67	1.78
PTCA on same day as CABG	2.71	<.001	2.55	2.88
Use of IABP prior to CABG	3.40	<.001	3.27	3.53
Number of Observations: 911,407 **C statistic**: 0.725				

* *Odds ratios associated with age categories are relative to patients aged 65-69 years*

† *Odds ratios associated with race are relative to white patients and patients in whom race was missing*

Appendix B) **Ratios of Observed to Predicted (O / P) Deaths for Individual states During Individual Years According to CON Status** *(* denotes if the O / P ratio is statistically significant)*

State	1994	1995	1996	1997	1998	1999
Continuous CON						
AK	1.59	0.30	1.34	1.43	1.11	0.33
AL	*1.19	0.99	1.01	*1.26	1.16	*1.18
AR	0.92	0.97	*1.25	1.17	1.16	1.15
CT	1.01	0.99	*0.75	0.87	1.07	0.88
DE	1.18	1.48	0.74	0.65	0.65	0.89
FL	0.93	1.01	*0.91	0.94	0.93	1.06
GA	*1.18	*1.30	*1.18	1.16	1.05	*1.22
HI	*1.74	1.12	*1.85	1.41	*1.48	1.47
IA	1.22	0.98	1.12	1.14	1.13	1.11
IL	*0.88	0.96	1.00	0.96	0.90	0.94
KY	1.03	1.02	1.16	1.15	1.02	*1.18
LA	1.17	1.05	1.12	1.13	*1.32	*1.38
MA	*0.78	*0.80	*0.70	*0.71	*0.57	*0.65
MD	0.84	1.05	0.94	0.99	0.96	0.99
ME	1.16	0.80	1.02	1.26	1.23	0.81
MI	0.88	0.92	0.93	0.97	0.97	*0.86
MO	0.92	1.02	0.96	1.04	1.01	0.94
MS	1.25	1.07	*1.45	1.25	1.13	1.25
MT	1.07	1.15	1.43	1.02	0.77	1.13
NC	*0.76	*0.77	0.91	0.99	0.98	*0.79
NE	1.27	*1.29	1.20	1.18	0.93	1.12
NH	0.89	0.71	0.83	0.70	0.69	0.97
NJ	0.98	1.11	*1.24	1.05	0.96	*0.83
NV	*1.80	*1.58	*1.33	*1.33	1.26	*1.43
NY	*0.63	*0.74	*0.74	*0.63	*0.61	*0.67
OH	1.09	0.95	0.89	0.90	1.08	*0.85
OK	*1.23	1.10	0.94	1.19	*1.47	*1.29

State	1994	1995	1996	1997	1998	1999
Continuous CON						
OR	1.13	1.16	0.93	0.90	0.77	1.13
RI	0.76	0.92	1.29	1.32	1.27	0.59
SC	1.11	*1.39	*1.28	*1.35	1.16	1.09
TN	0.89	0.93	1.00	0.92	1.09	*1.20
VA	*0.81	*0.62	0.86	*0.79	0.96	0.85
VT	0.86	0.91	1.09	0.71	1.30	*1.87
WA	1.06	0.94	1.02	1.04	1.08	1.13
WI	1.03	1.15	1.05	*1.27	1.09	1.01
WV	*0.74	0.93	1.03	0.88	1.00	1.10
DC	1.21	1.16	*1.35	0.91	0.90	0.94
No CON						
AZ	1.66	*1.25	*1.46	*1.24	1.09	*1.40
CA	0.98	0.95	*0.89	0.98	0.99	0.99
CO	0.94	1.12	1.19	0.92	0.77	*1.40
ID	1.29	1.24	*1.70	1.26	*1.99	*0.41
KS	0.95	*1.26	0.99	1.15	0.95	1.11
NM	0.93	0.86	1.38	1.17	1.01	1.16
SD	0.78	0.79	*0.60	*0.47	0.88	*0.33
TX	*1.43	*1.38	*1.30	*1.31	*1.35	*1.21
UT	1.24	1.19	1.11	*1.57	0.98	0.95
WY	1.35	1.14	1.15	1.34	0.85	0.90
Intermittent CON						
IN	0.87	0.98	1.02	0.86	*1.22	1.16
MN	0.97	1.14	0.84	0.94	0.93	0.87
ND	*1.54	0.83	1.13	0.85	0.93	0.95
PA	0.91	*0.85	*0.88	*0.83	*0.72	*0.79

Appendix C) Mean Annual Hospital CABG Volumes by State for Medicare Beneficiaries Aged 65 and Older During the Period 1994 through 1999

State	Mean Annual Volume	Number of Hospitals	State	Mean Annual Volume	Number of Hospitals
Continuous CON			*Continuous CON*		
AK	47	2	OK	129	15
AL	159	23	OR	154	11
AR	139	18	RI	269	2
CT	296	7	SC	173	12
DC	227	4	TN	207	25
DE	372	1	VA	182	19
FL	206	59	VT	278	1
GA	240	15	WA	157	15
HI	95	5	WI	142	25
IA	158	13	WV	338	5
IL	122	56			
KY	161	21	*No CON*		
LA	66	40	AZ	97	24
MA	249	13	CA	92	124
MD	236	8	CO	68	19
ME	400	2	ID	142	3
MI	208	31	KS	109	17
MO	132	37	NM	84	6
MS	110	12	SD	245	3
MT	143	4	TX	93	111
NC	231	21	UT	110	8
NE	156	9	WY	65	2
KY	161	21			
NH	200	4	*Intermittent CON*		
NJ	256	15	IN	137	29
NV	146	6	MN	157	15
NY	272	33	ND	104	7
OH	178	46	PA	180	60

Appendix D) CABG Utilization Rates per 1000 Medicare Beneficiaries Aged 65 Years and Older in Individual States for the Period 1994 through 1999

State	Average Number of Medicare Beneficiaries	Total Number of CABG Procedures During 1994-99 for State Residents	Average Annual Utilization Rate per 1000	Average Annual In-State Utilization Rate per 1000 (excludes out-of-state procedures)
Continuous CON				
AL	550,163	20,282	6.14	5.74
AK	32,605	723	3.70	2.67
AR	357,492	13,769	6.42	5.52
CT	455,803	12,341	4.51	4.21
DE	95,155	2,569	4.50	2.97
FL	2,474,750	66,379	4.47	4.07
GA	733,235	22,520	5.12	4.34
HI	146,960	2,636	2.99	2.90
IL	1,438,054	47,293	5.48	4.52
IA	427,560	12,979	5.06	4.06
KY	487,407	18,553	6.34	5.63
LA	494,756	14,919	5.03	4.84
ME	178,090	4,980	4.66	4.20
MD	560,495	14,604	4.34	2.93
MA	826,440	17,597	3.55	3.22
MI	1,192,624	38,806	5.42	4.98
MS	328,066	9,812	4.98	3.74
MO	734,787	23,287	5.28	4.95
MT	117,072	3,115	4.44	4.08
NE	226,462	7,484	5.51	4.85
NV	197,533	4,485	3.78	3.39
NH	143,987	3,968	4.59	3.53
NJ	1,064,596	26,054	4.08	3.22
NY	2,326,974	54,662	3.92	3.52

State	Average Number of Medicare Beneficiaries	Total Number of CABG Procedures During 1994-99 for State Residents	Average Annual Utilization Rate per 1000	Average Annual In-State Utilization Rate per 1000 (excludes out-of-state procedures)
Continuous CON				
NC	920,847	27,951	5.06	4.77
OH	1,474,607	45,922	5.19	4.73
OK	435,684	13,083	5.00	4.26
OR	428,343	9,291	3.62	3.32
RI	147,878	2,988	3.37	2.90
SC	451,965	13,413	4.95	4.14
TN	670,572	24,943	6.20	6.03
VT	74,236	1,824	4.10	2.11
VA	744,647	20,161	4.51	3.85
WA	633,368	13,338	3.51	3.23
WV	271,032	11,306	6.95	5.31
WI	689,230	21,089	5.10	4.61
DC	66,301	993	2.50	2.22
Overall	**22,599,767**	**650,119**	**4.79**	**4.23**
Average Rate for States			**4.71**	**4.04**

State	Average Number of Medicare Beneficiaries	Total Number of CABG Procedures During 1994-99 for State Residents	Average Annual Utilization Rate per 1000	Average Annual In-State Utilization Rate per 1000 (excludes out-of-state procedures)
No CON				
AZ	575,028	11,842	3.43	3.08
CA	3,366,853	64,671	3.20	3.13
CO	227,021	6,747	4.95	4.60
ID	140,873	3,856	4.56	2.64
KS	347,209	10,766	5.17	4.02
NM	194,640	3,685	3.16	2.23
SD	106,101	3,750	5.89	5.20
TX	1,933,116	54,525	4.70	4.59
UT	176,863	4,566	4.30	4.12
WY	56,169	1,598	4.74	2.14
Overall	**7,123,872**	**166,006**	**3.89**	**3.62**
Average Rate for States			**4.41**	**3.58**
Intermittent CON				
IN	731,674	22,850	5.20	4.47
MN	577,978	14,306	4.12	3.28
ND	92,750	3,005	5.40	4.93
PA	1,869,561	53,782	4.80	4.56
Overall	**3,271,962**	**93,943**	**4.78**	**4.33**
Average Rate for States			**4.88**	**4.31**